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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,822	REMACLE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45,48,50 and 52-89* is/are pending in the application.

4a) Of the above claim(s) *1-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,48,50 and 52-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/582817.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 August 2006 has been entered.

Election/Restrictions

2. Claims 1-44 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 September 2003.

Double Patenting

3. Claims 1-44 of this application conflict with claims 30, 34, 40, 41, 45, and 64 of Application No. 09/582,817. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 48, 50, 57-60, 64-69, 74-83, 88, and 89 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 48 is confusing as to how the metes and bounds of claim 45 has been modified as claim 45, as a result of the amendment of 01 August 2006 stipulates that the registered data is in "tracks or grooves." For purpose of examination, the expression "tracks or grooves" has been interpreted as being synonyms.

7. Claim 50 is confusing as to the nature of the structural relatedness of microchannels and chambers. Applicant is urged to consider the following expression: "which comprises microchannels and chambers wherein said microchannels fluidly connect said chambers."

8. Claim 57 is confusing in that it appears that the surface of the disc is to comprise aldehyde groups to which nucleic acids are to attach, yet claim 45, from which claim 57 depends, stipulates that the nucleic acid is already bound to said surface. Given such, there would not be an aldehyde group available. Similar issues exist with respect to claims 58 and 59.

9. Claim 60 is confusing as a result of the use of the expression "upon its surface." Claim 45 stipulates that there are at least two surfaces. Given the plurality of surfaces, it is not clear just which one is being referred to in claim 60. Similar issues exist with respect to claim 64.

10. Claim 65 is indefinite with respect to just what the "capture nucleic acid molecules" are "specific" for.

11. Claim 66 stipulates that the data bytes "are present in line on the disc surface." It is noted, however, that amended claim 45 stipulates that the data is in the disc's grooves or tracks, which are in a circle, not a line. Accordingly, it is not clear just what are the metes and bounds of the claim.

12. Claim 69 is confusing as to whether the "molded support" is in fact part of the disc, and if so, whether the surfaces of the support in their self create chambers or whether chambers are created out of some other structural relationship. It is also not clear how the support and disc relate to one another in terms of the binary data found in grooves and tracks, yet the same disc is to be divided into chambers.

13. Claim 74 is confusing as it seemingly imparts animate properties to an inanimate object. Specifically, it appears that the device "allows" some process to occur, or not occur; yet the device has not been defined in terms of comprising any logic analyzer.

14. Claims 76 and 77 are confusing as it is not clear if applicant is trying to invoke 112, sixth paragraph, when using the phrase "first reading head for," "second reading head for."

15. Claim 78 is confusing for while the claim comprises the expression "means for," the phrase is modified by the recitation of structure. Accordingly, it is not clear if applicant is seeking to invoke 35 USC 112, sixth paragraph. Similar issues exist with respect to claims 79 and 81-83.

16. Claim 89 is confusing with respect to the use of the phrase "the surface of the disc," as claim 45 specifically recites multiple surfaces. Accordingly, it is not clear just which of the

recited surfaces, or even possibly some other surface, e.g., the surface found within a chamber, that the phrase found within claim 89 is making reference to.

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 45, 48, 50, and 52-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

19. Claims 45-88 are drawn to the following inventions:

- Claims 45-69 are drawn to a disc comprising registered data
- Claims 70-72 and 87 are drawn to a method of making a disc;

- Claims 73, 86, and 88 are drawn to a kit;
- Claims 74-80 are drawn to a detection and/or reading device; and
- Claims 81-84 are drawn to a handling device for a disc.

A review of the disclosure finds the following examples:

Examples

Example 1: Detection of DNA on CD

Example 2: Detection of DNA on CD with laser detection

Example 3: Detection of protein on CD by light absorption

Example 4: Detection of protein Chips on CD with colorimeric labeling

Example 5: Detection of auto-immune antibodies on CD

Example 6: Magnetic detection of DNA or protein on CD

Example 7: Detection of several bacterial species and their genus by DNA microarrays present on the CDs

Bio-CD™ spotting

Example 8: Detection of gene expression on microarrays present on the CDs: exemple of HepatoChips

HepatoChips Design: Fifty-nine genes microarray

Example 9: Multiple sample analysis in the different molded chambers present on the same disc platform.

Example 10: Steps performed by the automate in the hybridization chamber.

Example 11: Olefinic oxidation

Example 12: Steps performed by the automate in the extraction, dilution, amplification and hybridization chamber.

Example 13: Target detection trough the reflective layer of a CD with one laser illumination beam and two detectors

Example 14: Description of a fluorescent reading device

Example 15: Detection of protein upon the disc according to the invention with colorimeric labeling

Example 16 : Detection of auto-immune antibodies upon the disc according to the invention

20. The claimed invention has been amended so to require the presence of at least single stranded nucleic acids that are to serve as capture molecules, and that the CD or DVD comprises binary information that is to be read at the same time the hybridization results are. None of the examples provided disclose such a CD or DVD, much less a method of performing both aspects of the method. Similarly, none of the examples provide an adequate written description of any device capable of making such a CD or DVD or reading it, or capable of carrying out all phases of any related assay. Additionally, the examples provided fail to provide an adequate written description of the full genus of discs claimed. Furthermore, it is noted that none of the "capture molecules" are impervious to any and all forms of cleavage, an embodiment encompassed by the claims.

21. The specification also does not provide an adequate written description of those nucleic acids that are useful such that one of skill in the art would be able to recognize those embodiments that are useful from those that are not.

22. While Example 8 teaches of using the "Rat HepatoChips ™ (AAT, Namur, Belgium)," and page 61 describes the nucleic acids as being "single stranded DNA probes attached to the glass by a covalent link," and Table 2 defines the target molecule in terms of certain genes and

how they are believed to function, such does not provide an adequate written description of the immobilized nucleic acids, as such again speaks to functional attributes, and not physical or chemical properties that would allow a skilled artisan to recognize one sequence as being encompassed, or not encompassed, by the claims. Further, the record does not support the position that applicant possessed the nucleotide sequence for any and all target molecules, which fairly encompass any nucleic acid sequence that correlates with intelligence, aging, as well as correlating with any disease of any etiology, for any and all life forms.

23. It is noted that claim 55 and 56 recite the density of the arrays (claim 55), as well as the number of arrays provided per sample. Said claims have no upper limit on density or on the number of arrays per sample. A review of the disclosure fails to find where the full scope of the claims has been adequately described so as to reasonably suggest that applicant was in possession of the invention at the time of filing. Furthermore, the specification has not been found to provide an adequate written description of even one disc, be it a CD or DVD, which has the minimum number of arrays and the minimum density of said arrays, wherein said disc also has binary information and can be read subsequent to any hy6bridization reaction and wherein said reading is to be performed by the same device.

24. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

25. As seen in claim 67, "the alignment of capture molecules is converted into digital information selected from the group consisting of words, numbers, music, software and data bases." A text search of the corresponding patent application publication (US Patent Application Publication 2002/0177144) fails to find an adequate written description of said "words, numbers, music, software and data bases." Indeed, the very concept expressed in claim 67 is not to be found in the specification.

26. For purposes of examination, claims 74-80, directed to a detection and/or reading device, have been construed as encompassing a "disc" that can be of virtually any shape, that the registered data and capture assay may be on the same side, opposite sides, as well as allowing for the assay to be conducted internal to the "disc." Additionally, the CD that the device is to read may well have additional coatings over the surface of the disc, which may include coatings of the disc, prior to the attachment of capture moieties, as well as coatings/precipitates subsequent to a binding reaction having taken place. Given this breadth of interpretation, the specification has been found to be essentially silent as to how a CD reader is to be manipulated to read both sides of a disc, and to be able to interpret the clusters of signal, when normal CD readers are interpreting pits found in grooves- which is where the registered binary data is stored.

27. Similar issues of non-disclosure are found with respect to claims 85, drawn to an apparatus for performing he method of claim 44, and the handling device of claims 81-84.

28. Claims 73, 86, and 88, drawn to kits, are not adequately supported by the disclosure. It is noted with particularity that applicant is claiming compositions of matter. While the claims

recite "reactants allowing the binding between a target molecule and its capture molecule," such speaks to how they are to perform, however, such language does not allow one to identify which compounds are encompassed by the claim and which are not.

29. In view of the scope of the amended claims, the limited disclosure provided, and the absence of convincing evidence to the contrary, claims 45, 48, 50, and 52-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 45, 48, 50, and 52-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737,

8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

The quantity of experimentation necessary

The amount of experimentation required is on the order of several man-years, with little, if any reasonable expectation of success.

The amount of direction or guidance presented

The amount of guidance provided is limited, and then not commensurate with the scope of the claims.

The presence or absence of working examples

A review of the disclosure finds the following examples:

Examples

Example 1: Detection of DNA on CD

Example 2: Detection of DNA on CD with laser detection

Example 3: Detection of protein on CD by light absorption

Example 4: Detection of protein Chips on CD with colorimeric labeling

Example 5: Detection of auto-immune antibodies on CD

Example 6: Magnetic detection of DNA or protein on CD

Example 7: Detection of several bacterial species and their genus by DNA microarrays present on the CDs

Bio-CD™ spotting

Example 8: Detection of gene expression on microarrays present on the CDs: exemple of HepatoChips

HepatoChips Design: Fifty-nine genes microarray

Example 9: Multiple sample analysis in the different molded chambers present on the same disc platform.

Example 10: Steps performed by the automate in the hybridization chamber.

Example 11: Olefinic oxidation

Example 12: Steps performed by the automate in the extraction, dilution, amplification and hybridization chamber.

Example 13: Target detection trough the reflective layer of a CD with one laser illumination beam and two detectors

Example 14: Description of a fluorescent reading device

Example 15: Detection of protein upon the disc according to the invention with colorimeric labeling

Example 16 : Detection of auto-immune antibodies upon the disc according to the invention

The claimed invention has been amended so to require the presence of at least single stranded nucleic acids that are to serve as capture molecules, and that the CD or DVD comprises binary information that is to be read at the same time the hybridization results are. None of the examples provided disclose such a CD or DVD, much less a method of performing both aspects of the method. Similarly, none of the examples provide an adequate written description of any device capable of making such a CD or DVD or reading it, or capable of carrying out all phases of any related assay. Additionally, the examples provided fail to provide an adequate written description of the full genus of discs claimed. Furthermore, it is noted that none of the "capture

molecules" are impervious to any and all forms of cleavage, an embodiment encompassed by the claims.

The state of the prior art

The state of the prior art is limited s it relates to combining both nucleic acid assays with a support that is to retain functional binary information

The predictability or unpredictability of the art

The claimed invention relates directly to the synthesis of arrays on a support that also comprises binary information that needs to be accessed and acted upon while the hybridization assay is taking place, and or the results are being collected and interpreted.

At column 40 of Jones (US Patent 5,858,671) the inherent obstacle in synthesizing oligonucleotide arrays is disclosed. As stated therein, "that even if the constituent enzymatic steps approach 100% completion, incompletely processed products can accumulate to significant levels. For example, during oligonucleotide synthesis of a 70-mer, requiring 69 couplings, a 99% coupling efficiency results in only 50% of the generated oligonucleotides being full length ($0.99^{69} = 0.50$)." In the present case, applicant is claiming a product that would be the result of an infinite number of couplings, not just 69 as described above.

Zhang et al., *Bioinformatics*, Vol. 19, No. 1, 2003, page 14, states:

> It is widely recognized that the hybridization process is prone to errors and that the future of DNA sequencing by hybridization is predicated on the ability to successfully cope with such errors. However, the occurrence of hybridization errors results in the computational difficulty of the reconstruction of DNA sequencing by hybridization. The reconstruction problem of DNA sequencing by hybridization with errors is a strongly NP-hard problem. So far the problem has not been solved well.

Chan (US Patent Application Publication US 2002/0119455 A1):

[0018] In practice, Probe Up methods have been used to generate sequences of about 100 base pairs. Imperfect hybridization has led to difficulties in generating adequate sequence. Error in hybridization is amplified many times. A 1% error rate reduces the maximum length that can be sequenced by at least 10%. Thus if 1% of 65,536 oligonucleotides gave false positive hybridization signals when hybridizing to a 200-mer DNA target, 75% of the scored "hybridizations" would be false (Bains, 1997). Sequence determination would be impossible in such an instance. The conclusion is that hybridization must be extremely effective in order to generate reasonable data. Furthermore, sequencing by hybridization also encounters problems when there are repeats in sequences that are one base less than the length of the probe. When such sequences are present, multiple possible sequences are compatible with the hybridization data. (Emphasis added.)

The invention also relates to conducting amplification reactions in the chamber, as well as hybridization reactions with the single stranded nucleic acid capture molecules. As set forth in Carrico, (US Patent 5,200,313) the extent and specificity of hybridization is affected by the following principal conditions:

- The purity of the nucleic acid preparation.
- Base compositions of the probe - G-C base pairs will exhibit greater thermal stability than A-T or A-U base pairs. Thus, hybridizations involving higher G-C content will be stable at higher temperatures.
- Length of homologous base sequences- any short sequence of bases (e.g., less than 6 bases), has a high degree of probability of being present in many nucleic acids. Thus, little or no specificity can be attained in hybridizations involving such short sequences. From a practical standpoint, a homologous probe sequence will often be between 300 and 1000 nucleotides.

- Ionic strength- the rate of reannealing increases as the ionic strength of the incubation solution increases. Thermal stability of hybrids also increases.
- Incubation temperature- Optimal reannealing occurs at a temperature about 25 - 30 °C below the melting temperature for a given duplex. Incubation at temperatures significantly below the optimum allows less related base sequences to hybridize.
- Nucleic acid concentration and incubation time- Normally, to drive the reaction towards hybridization, one of the hybridizable sample nucleic acid or probe nucleic acid will be present in excess, usually 100 fold excess or greater.
- Denaturing reagents- the presence of hydrogen bond-disrupting agents, such as formaldehyde and urea, increases the stringency of hybridization.
- Incubation- the longer the incubation time, the more complete will be the hybridization.
- Volume exclusion agents- the presence of these agents, as exemplified by dextran and dextran sulfate, are thought to increase the effective concentrations of the hybridizing elements thereby increasing the rate of resulting hybridizations.
- Further, subjecting the resultant hybridization product to repeated washes or rinses in heated solutions will remove non-hybridized probe. The use of solutions of decreasing ionic strength, and increasing temperature, e.g., 0.1X SSC for 30 minutes at 65 °C, will, with increasing effectiveness, remove non-fully complementary hybridization products.

The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001 in hat the specification does not reasonably suggest that applicant had possession of the requisite starting materials, e.g., a CD or DVD with the requisite binary information and arrays of single

stranded nucleic acids, and which are to be used in a hybridization reaction, and wherein said CD or DVD has both binary information and nucleic acid hybridization products read by a reader.

As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
>
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed non-enabled by the disclosure.

Claim Rejections - 35 USC § 102

30. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claimsn74 and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,418,910 (Siegel).

32. Claims 74 and 75 have been interpreted and encompassing a CD reader. Siegel, column 1, teaches of a "CD reader." Such a disclosure is considered, in the absence of convincing evidence to the contrary, to anticipate at least one embodiment of the claimed invention.

Claim Rejections - 35 USC § 103

33. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

34. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

35. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

36. Claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.).

37. Wang et al., teaches at length of using discs (applicant's CDs and DVDs) for conducting hybridization assays. As see in column 10, the disc comprises arrays of binding moieties are present. DNA is specifically identified. The discs are subject to reading by a disc-reading device, which can comprise a laser source, a beam splitter, which speaks to the presence of multiple detector units present. Also disclosed is the use of spinning of the disc in relating to a scanner to different sites along a given track and a linear motor that moves the scanner along a

radial direction to scan over the entire disk. Column 6, second paragraph, specifically references the use of CDs.

38. Column 3 speaks directly to having functionalized groups on a surface of the disc, and that nucleic acids can be covalently bound to it through such functional groups, which are known in the art.

39. Column 14, penultimate paragraph, teaches explicitly of the incorporation of arrays, and that they may take a variety of forms. Column 14, last paragraph, teaches explicitly of the disc being divided into separate coded addressable sections, and that the beginning of a sector can comprise information about the given section.

40. Wang et al., column 13, discloses the disc further comprising microchannels.

41. Wang et al., has not been found to recite specific densities of the arrays, nor the number of arrays one would prepare for a given sample, however, such limitations are not deemed to rise to the level of a patentable distinction but rather, constitute the end result of routine optimization. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re Aller, Lacey, and Hall*, 105 USPQ 233 (CCPA 1955):

> Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. In re Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931, 24 USPQ 52; In re Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. In re Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; In re Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. In re Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627,

> 25 USPQ 433; In re Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; In re Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11, 57 USPQ 136. (Emphasis added)

In view of the detailed teachings provided by Wang et al., one of ordinary skill in the art at the time the invention was made would have been amply motivated to have adopted the method, disc, and devices of Wang et al., so to have a disc that comprises arrays of any desired density and multiplicity so that any target sequence of interest would be detected. Said detailed disclosure would have also instilled a reasonable expectation of success in developing said methods, discs, and related devices.

42. Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of 5,160,626 (Pemawansa et al.).

43. See above for the basis of the rejection as it relates to the disclosure of Wang et al.

44. While Wang et al., teach broadly of bonding nucleic acids to a support through functional groups found on its surface, they do not specifically teach using aldehyde groups.

45. Pemawansa et al., claim 17, specifically recites linking nucleic acids to a support through aldehyde groups.

46. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Wang et al., with that of Pemawansa et al., as Pemawansa et al., teach of a specific embodiment by which the nucleic acids can be immobilized

to the surface of a support structure. In view of such explicit teachings, said ordinary artisan would have been both amply motivated and have had a most reasonable expectation of success.

47. For the above reasons, and in the absence of convincing evidence to the contrary, claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of 5,160,626 (Pemawansa et al.).

48. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.), as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 5,800,992 (Fodor et al.).

49. See above for the basis of the rejection as it relates to the disclosure of Wang et al.

50. While Wang et al., teach broadly of bonding nucleic acids to a support through functional groups found on its surface, they do not specifically teach using acrylate groups.

51. Fodor et al., column 46, teaches of binding DNA to acrylate groups found on the surface of a substrate.

52. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Wang et al., with that of Fodor et al., as Fodor et al., teach of a specific embodiment by which the nucleic acids can be immobilized to the surface of a support structure. In view of such explicit teachings, said ordinary artisan would have been both amply motivated and have had a most reasonable expectation of success.

53. For the above reasons, and in the absence of convincing evidence to the contrary, claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al., as applied to

claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 5,800,992 (Fodor et al.).

54. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 4,542,102 (Dattagupta et al.).

55. See above for the basis of the rejection as it relates to the disclosure of Wang et al.

56. While Wang et al., teach broadly of bonding nucleic acids to a support through functional groups found on its surface, they do not specifically teach linking nucleic acids to the support via photoactivatable groups.

57. Dattagupta et al., teaches at length various methods by which nucleic acids can be coupled to a support through the action of photoactivatable groups.

58. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of photoactivatable groups in the disc of Wang et al., as such would have afforded the ordinary artisan a highly efficient and effective means by which nucleic acids can be coupled to a given support.

59. In view of the detailed teachings provided by the prior art of record, said ordinary artisan would have also had a most reasonable expectation of success. Therefore, and in the absence of convincing evidence to the contrary, claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,617 (Wang et al.) as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 4,542,102 (Dattagupta et al.).

60. Claims 72 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al., as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 5,556,748 (Douglas).

61. See above for the basis of the rejection as it relates to the disclosure of Wang et al.

62. While Wang et al., teach broadly of bonding nucleic acids to a support through functional groups found on its surface, they do not specifically teach using a masking group such as albumin.

63. Douglas, column 3, bridging to column 4, teaches explicitly of binding DNA to a plastic surface that has functional groups on it, and that the areas surrounding the bound nucleic acids can be coated with protective materials such as albumin. This teaching meets a limitation of claims 72 and 87.

64. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the use of albumin as a protective layer on the discs of Wang et al., as such would have minimized the non-specific binding of reactants with the disc's surface, thereby resulting in more reproducible and accurate assays.

65. In view of the detailed disclosures, said ordinary artisan would have also had a most treasonable expectation of success.

66. For the above reasons, and in the absence of convincing evidence to the contrary, claims 72 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al., as applied to claims 45, 48, 50-56, 59-69, 71, 73-82, 84, and 88-89 above, and further in view of US Patent 5,556,748 (Douglas).

Conclusion

67. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

68. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

69. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS